

UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

SERIAL NUMBER	FILING DATE	FIRST NAM	MED APPLICAN	T	ATTORNEY DOCKET NO
24,111	03/26/79	Yasuhide Ta	chi et	al.	A13132P1
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PTOL-326 (rev. 7-79)

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The finality of the rejection dated March 10, 1980 is hereby removed in view of the newly cited reference. It is the Examiner's position that the reference is necessary in order that a proper resolution of the issue of patentability be obtained.

Claim I is the sole claim in the case. Claim 1 is rejected under 35 U.S.C. 103 as being obvious from the disclosure of Ercoli et al. in combination with Elks et al. (2) , @ newly cited. The primary reference discloses the 17.21-d', ester of hydrocortisone at column 4, lines 4 and 9. The secondary reference discloses the fact that the anti-derivative could be enhanced, with little risk of disturbance of the mineral balance and other systemic activity should the compound be absorbed, by preparing the 17 -mono and 17,21-diesters of the parent compound. The reference teaches the method of preparing said esters and shows the procedures of introducing an ester function at C-21 which is the same or different from the function at C-17. In view of the teaching of the secondary reference, it is Examiner's position that the 17 -butyrate-21-proprionate deester derivative of



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Ercoli et al's compound would be obvious to one skilled in the art; especially in view of the fact that Example 29 specifically shows the combination.

Applicants arguments as well as the declarations placed of record have been carefully considered but are not deemed to be of such a magnitude as to be persuasive of patentability, The affidavits placed of record to establish patentability have no probative value since they fail to overcome the teachings of the secondary reference. It appears to the Examiner that the advantage relied upon for patentability by applicants would be inherently present in the reference since Example 29 shows the same di-ester combination. It would be interesting to find out what observations could be made when comparing the biological properties of beta methasone 17-valerate-21-acetate a against the compound in Example 29. In all probability the therapeutic effectiveness of the di-acylate in Example 29 would be about 10 times greater than that of the 17-valerate-21-acetate of the beta methasone. In view of the extensive teachings of the prior art, the specifically claimed compound is deemed a modification of a well known anti-inflammatory compound that would be obvious to those skilled in the field of steroids.

This application should be <u>prepared</u> for Final Rejection. S.S.P. (3 months)

Primary Examine,

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